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November 15, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Attention: Box PCT - DESIGNATED/ELECTED OFFICE (DO/EO/US)

FORM PTO-1390 (REV 5-93) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER 32143-152042
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1 5)
INTERNATIONAL APPLICATION NO. PCT/FR98/00984	INTERNATIONAL FILING DATE May 15, 1998	PRIORITY DATES CLAIMED: May 15, 1997
TITLE OF INVENTION - see attached pages -		
APPLICANT(S) FOR DO/EO/US - see attached pages -		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. X This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. X This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(l).

– See attached pages for additional data –

November 15, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney Docket: 32143-152042

Attention: PCT-DO/US

Re: International Application PCT/FR98/00984 filed May 15, 1998
Priority Claimed: French Application 97/06082 filed on May 15, 1997

Inventor: **Maïwenn BONNET**
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Title: PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARATUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION

Sir:

Submitted herewith, as the first submission, are the following for the purposes of entering the national stage for the USA under 35 U.S.C. 371(c)**, immediate national examination under 35 U.S.C. 371(f) being requested**.

- International application PCT/FR98/00984 published as WO 98/51472 with English-language International Search Report issued by the European Patent Office.
- English-language translation of the international application.
- Preliminary Amendment to eliminate multiple claim dependency.
- Small Entity Declaration
- Information Disclosure Statement, Form PTO-1449 and (2) cited references.
- Preliminary Examination Report.
- Filing fee of $564.00.

TOTAL FEE ENCLOSED: $564.00

Should no remittance be attached, or should a greater or lesser fee be required, please charge or credit our Account No. 22-0261.

Respectfully submitted,

John W. Schneller

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#169769

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Maïwenn BONNET et al.

International Appln. No.: PCT/FR98/00984

Filed: Concurrently herewith Attorney Dkt. No.: 32143-152042

For: PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARATUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination of the application, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please delete page 5, without prejudice, and insert the following as page 5 --model is very fragile. It must be handled all the more delicately, which requires more care and time. Finally, the procedure generates noise, dust, and odors (solvents, etc.).

Attempts at thermoforming have been made in order to be freed from some of the disadvantages linked to the traditional procedure. The thermoforming technique is widely used for producing orthodontic apparatuses and is described in many general works.

In the domain of orthodontics, the document DE 36 10 349 may be mentioned. It describes a process and mechanism to create an orthodontic apparatus. The base material is

present in the form of a plastic film with constant thickness, maintained by film supports which undergo deformation through the addition of heat and applied pressure, until a model is created based on casting taken directly from the patient.

Michel AMORIC's publication: "Gouttieres orthodontiques et orthopédiques thermoformées" *Thermoformed orthodontic and orthopedic splints*, 1993, Editions SID can also be mentioned. The principle behind this technique is that one uses a flat plate as a base material with a constant thickness. Starting with a traditionally produced mold the plate is deformed so as to obtain an apparatus having an appropriate shape.

Not all apparatuses can be obtained by this method. In particular, this method is not efficient for apparatuses having a hollow body and variable thickness. The stretching that the plate must withstand in these specific cases is considerable and therefore difficult to obtain without tearing. Most of all, thicknesses cannot be controlled since they are simply dependent on the stretching necessary to obtain the desired shape and are therefore irregular since not all areas are stretched in the same manner. This technique is therefore not appropriate for a certain number of cases.

The variant consisting in the use of a two part apparatus, that is, two base plates yielding two half-apparatuses that are assembled is also not adequate. It allows a decrease in the stretching undergone by the plates, and therefore in the risks of ripping and the problems of too irregular thicknesses, but the problem is in part displaced to the assembly of the two half-apparatuses obtained. In effect, the difficulty lies in the precision and solidity of the glued or soldered assembly, inasmuch as one must also install in this assembly area the fastening hooks for the fastening of the apparatus in the patient's mouth. --

IN THE CLAIMS:

Please amend claims 1-34 and add claims 35 and 36 as follows:

1. (Amended) A [P]preform allowing for the obtainment, after deformation, [customized] a personalized orthodontic of [orthopedic dentofacial appliance] dentofacial orthopedic apparatus characterized [in that it has the general form] by a three-dimensional hollow body [and in that] which has a form that allows [its] the preform's expansion inside a mold reproducing the morphology of the patient.

2. (Amended) The [P]preform according to claim 1, [characterized in that] wherein [is] has a hollow tubular or approximately tubular shape.

3. (Amended) The [P]preform according to [any of claims 1 through 2] claim 1, characterized [in that is has a] by a hollow, tubular or approximately tubular shape[,] and is cut [out at the top front] on the upper anterior part to form an opening 8.

4. (Amended) The [P]preform according to [any of claims 1 through 3] claim 1, characterized by the fact [in] that it is [made of a plastic material of the thermoplastic or thermosetting type deformable by] manufactured in thermoplastic or thermosetting plastic material which is deformable through expansion.

5. (Amended) The [P]preform according to claim 4, characterized by the fact [in] that it is [made of a] manufactured using a thermoplastic plastic material chosen [from] in the group constituted [by] of polyethylene, polypropylene, polycarbonate[s], methyl polymethacrylate, PVC, polyurethanes, or [of a] using a thermosetting plastic material chosen [from] in the group constituted by methyl polymethacrylate and polyurethanes.

6. (Amended) The [P]preform according to [any of claims 1 through 5] claim 1, characterized [in that it has on the] by a surface [guiding means, for example bosses or recesses,

intended to guide the operator during the cutting operation, and/or pre-drilled holes (7) used to contain the adhesive paste for the functional appliance] with guides such as bumps or recesses intended to guide the technician during cutting operations and/or initial holes (7) that are used to hold the fastening hooks of the finished dentofacial appliance.

7. (Amended) The [P]preform according to [any of claims 1 through 6] claim 1, characterized [in] by the fact that it is [produced in unrolled] manufactured in a flat, developed shape [form before] prior to being [shaped] given shape by [the operator] a technician.

8. (Amended) The [P]preform according to [any of the preceding claims] claim 1, [allowing the obtainment] yielding, after deformation, [of] a [Bonnet night lingual retainer (N.L.R.)] Bonnet's Nighttime Lingual Envelope or N.L. E.

9. (Amended) A [P]process for [producing] the production of a [customized] personalized orthodontic or [orthopedic dentofacial] dento-facial orthopedic [appliance] apparatus, [characterized in that it comprises contains] the following [stages] steps:

- [production of an expansion] comprising creation of a female mold (9, 10) [made] based at least [partially from a design] in part on study models [model or models made] created by [the] a practitioner from the [impression or impressions taken] casting or castings made from his patient,

- positioning [of] the preform (1) [according to any of claims 1 through 8] of claim 1 in the [expansion] female mold,

- expansion of the preform until it has reached the desired shape,

- [demolding of the appliance obtained, which] ejection from the mold of the obtained apparatus which becomes functional after finishing.

10. (Amended) The [P]process according to claim 9, characterized [in] by the fact that the expansion [takes place] is performed with heat and [in] that the preform is brought to the [softening point] deformation temperature of its [constituent] constitutive material [before] prior to the expansion stage, [either before or after the positioning stage in the expansion mold].

11. (Amended) The [P]process according to claim 10, characterized [in] by the fact that the [reaching of the] expansion temperature is [produced] attained by the action of [a] radiation or a heat[-exchanging liquid] bearing fluid.

12. (Amended) The [P]process according to claim 11, characterized in that the radiation used is of the microwave or ultraviolet or infrared type.

13. (Amended) The [P]process according to [any of claims 9 through 12] claim 9, characterized [in] by the fact that the expansion is [produced] performed by any appropriate [means for obtaining] method to obtain the expansion of the preform to the desired shape.

14. (Amended) The [P]process according to claim 13, characterized [in] by the fact that the expansion is [produced] performed by the action of an expansion fluid or mechanically.

15. (Amended) The [P]process according to claim 14, characterized [in] by the fact that the expansion fluid is compressed air or water.

16. (Amended) The [P]process according to [any of claims 9 through 15] claim 9, characterized [in] by the fact that the expansion [is produced by means] takes place through the intermediary of an [expanding] expansion core (14) placed in the preform (1) and inflated by the expansion fluid.

17. (Amended) The [P]process according to claim 16, characterized in that the core [has] is a controlled expansion core (16).

18. (Amended) Process according to claim 16 [or 17], characterized [in that the] by an [expanding] expansion core (14,16) [is] made of a material resistant to the expansion temperature, [[for example] such as an elastomer material].].

19. (Amended) Process according to [any of claims 9 through 18] claim 9, characterized [in] by the fact that the preform is made of thermosetting material and in that the expansion stage is simultaneously or [subsequently] later accompanied by a [stage] step for [polymerizing] polymerization of the thermosetting material.

20. (Amended) The [P]process according to [any of claims 9 through 19] claim 9, characterized [in] by the fact that it [also comprises, during the expansion, the] further comprises, insertion by duplicate molding of fastening pieces or [complementary] additional pieces during expansion.

21. (Amended) The [P]process according to [any of claims 9 through 20] claim 9, characterized [in] by the fact that the finishing [stage comprises] step includes at least one of the following actions: [creation] preparation of one or more openings, polishing, anchoring of fastening hooks, [attachment] setting of [complementary] additional pieces, elimination of [the unnecessary] useless parts, reduction of the surface [of] in certain areas.

22. (Amended) The [P]process according to [any of claims 9 through 21] claim 9, characterized [in] by the fact that it [comprises] includes a [stage] step for anchoring the fastening hooks [at] in movable [anchor] anchoring points.

23. (Amended) The [P]process according to [any of claims 9 through 22] claim 9, characterized [in] by the fact that the [orthodontic or] dento-facial orthopedic [dentofacial appliance] or orthodontic device obtained by the process [during a previous] in the preceding cycle is used as a preform.

24. (Amended) The [P]process according to [any of claims 9 through 23] claim 9, characterized [in] by the fact that the [customized] personalized orthodontic or [orthopedic dentofacial appliance] dento-facial orthopedic apparatus obtained is a [Bonnet night lingual retainer (N.L.R.)] Bonnet's Nighttime Lingual Envelope or N.L.E.

25. (Amended) [Expanding] An expansion core[, characterized in that it is used in a] appropriate for implementation of a process according to [any of claims 16 through 24] claim 16[,] and [in that it comprises] containing at least one means [for] of controlling its expansion.

26. (Amended) An expansion core [Core] according to claim 25, [characterized in by the fact that the means for] wherein the method of controlling its expansion is chosen from among the following [means] methods, [i.e.] an increase in the thickness of its wall in certain areas and the [insertion into] introduction in its wall of rigid[, for example metal,] reinforcements.

27. (Amended) An [E]expansion [device characterized in that it allows the expansion of the preform] mechanism appropriate for the implementation of a process according to [claims 1 through 8 until it has reached] claim 9 and adapted so that the preform reaches the desired shape[, through the] by displacement of mechanical [parts moved] pieces changed by the [operator] technician during the expansion phase.

28. (Amended) A [F]fastening hook for an orthodontic or [orthopedic dentofacial appliance produced] dento-facial orthopedic apparatus according to the process described in [claims 9 through 24] claim 9[, characterized in that it comprises a branch called a return branch that] based on a preform made of a thermoplastic plastic material characterized by the fact that it contains a segment called a bent-back segment which remains outside the [appliance after] apparatus at the end of insertion.

29. (Amended) A [D]device for attaching fastening hooks [to] on an orthodontic or [orthopedic dentofacial appliance] dento-facial orthopedic apparatus [produced] manufactured according to the process described in [claims 9 through 24] claim 9[,] characterized [in that it comprises] by a [device] mechanism for supplying electrical heating energy and [for] stable mechanical positioning of the fastening hook to be anchored.

30. (Amended) A [Device] mechanism according to claim 29, characterized [in] by the fact that the [supply of] electrical energy is [provided] supplied [either] by a portable current generator [hand-held] held by the hand of a technician [by the operator] and [comprising] containing two rigid electrical conductors, [or by a gun that mechanically [holding] holds a pair of rigid electrical conductors connected by flexible conductors to a fixed generator].

31. (Amended) A [Device] mechanism according to [claim 29 or 30] claim 29, characterized [in] by the fact that the stable mechanical positioning is [performed] done [by] with the ends of [the] electrical conductors[,] which have [the form of a clip or] a clamp shape, adapted to the diameter of the wire or to the shape of the hook to be inserted, for example a fork shape.

32. (Amended) A [P]process according to claim 22, characterized [in] by [that the] fastening hooks [are] attached [according to claim 28 by means of an attaching device according to any of claims 29 through 31] using a fastening mechanism.

33. (Amended) [Customized] A personalized orthodontic or [orthopedic dentofacial appliance] dento-facial orthopedic apparatus, characterized [in] by the fact that it is [produced] manufactured [from a] based on a preform (1) according to [any of claims 1 through 8] claim 1 [by means of a process according to any of claims 9 through 24 and 32].

34. (Amended) A personalized [O]orthodontic or [orthopedic dentofacial appliance] dento-facial orthopedic apparatus according to claim 33, characterized [in that it constitutes] by a [Bonnet night lingual retainer (N.L.R.)] Bonnet's Nighttime Lingual Envelope or N.L.E.

--35. The process according to claim 18, wherein the material registrant to expansion temperature is an elastomer. --

--36. A mechanism according to claim 29, characterized by the fact that the electrical energy is supplied by a gun that mechanically holds a pair of rigid electrical conductors connected by flexible conductors to a fixed generator. --

REMARKS

Claims 1-36 are pending in this application. By this Amendment, claims 1-34 are amended to better define the subject matter that Applicants regard as their invention and/or to delete multiple dependency and claims 35 and 36 are added to conform with U.S. Patent and Trademark Office practice and procedure.

Respectfully submitted,

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Date: November 15, 1999

#169725

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Maïwenn BONNET et al.

Appln. No. : 09/423,858 International Appln. No.: PCT/FR98/00984

I.A. Filing Date: 05/15/98 Attorney Dkt. No.: 32143-152042

For: PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARATUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION

Date: February 25, 2000

SECOND PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the application, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Page 1, after line 5, insert the following new section:

--CROSS-REFERENCE TO RELATED APPLICATION

This application is related to International Application No. PCT/FR98/00984, filed May 15, 1998, the entire specification of which is incorporated herewith by reference. --

Page 3,line 2, after "radii" insert --. Therefore, the technician is confronted with several difficulties--.

Page 16, after line 16 insert a new paragraph --So that because of these structural differences in relation to the spherical core, the role of the controlled expansion core is more complex than the preform's single expansion. --

Page 21, after line 24 insert a new paragraph --The fastening hooks or complementary pieces can also be anchored during the second transformation, where it is the expansion itself that creates anchoring overmoldings, fastening hooks or complementary pieces.--

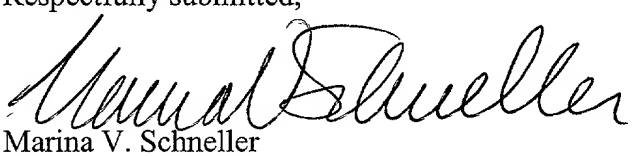
IN THE DRAWINGS:

Replace pages 2/8 and 3/8 (figures 2A, 2B, and 2C) with substitute pages 2/8 and 3/8, wherein the French language text in the original drawings ("avant" and "arrière") have been replaced with their English language translations ("front" and "rear"), as shown on page 1 of the PCT parent application.

REMARKS

Claims 1-36 are pending in this application. By this Amendment, the Specification is amended to incorporate text that erroneously omitted in the English-language translation filed on November 15, 1999. To comply with the Notice of Defective Translation, the French text in the figures has been translated and substitute figures have been submitted.

Respectfully submitted,



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MVS/MJF

Applicant or Patentee: Malwenn BONNET et al.
Serial or Patent No.: Attorney Docket No.: 32143-152042
Filed or Issued:
For: PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARATUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I qualify as an independent inventor as defined in 37 CFR 1.9(c), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled:
PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARATUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION
described in:

- ☒ the specification filed herewith.
- ☐ application serial no. _____, filed _____
- ☐ patent no. _____, issued _____

I have not assigned, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☐ no such person, concern, or organization.
- ☐ persons, concerns or organizations listed below:*

NOTE: Separate statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27).

FULL NAME
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

Malwenn BONNET	François BONNET	Bruno BONNET
Signature of Inventor	Signature of Inventor	Signature of Inventor
Date 14/11/99	Date 10/11/99	Date 10/11/99

PREFORM, WHICH, AFTER DEFORMATION, ALLOWS THE PRODUCTION OF PERSONALIZED ORTHODONTIC OR DENTO-FACIAL ORTHOPEDIC APPARATUSES , THE OBTAINED APPARATUSES, AND THEIR PRODUCTION PROCESS.

This invention concerns the orthodontic or dento-facial orthopedic apparatus sector, particularly those which are precisely adapted to the specific morphology of each patient.

More particularly, it concerns all orthodontic or dento-facial orthopedic apparatuses having a general hollow body which may have one or more openings, variable thickness, and which, due to this particular geometry, cannot be produced from a flat plate.

Such apparatuses, which may be removable, may be those intended to maintain a patient's tongue in a given volume, particularly Bonnet's Nighttime Lingual Envelope or N.L.E..

More generally, the invention concerns apparatuses which must necessarily be adapted very precisely to each patient or user in order to fulfill their function and which cannot be manufactured based on a blank in the form of a flat plate due to their final complex shape (open hollow body, variable thicknesses which cannot be obtained by simply shaping a plate, etc.). By contrast, these apparatuses are produced starting from a blank or preform whose shape permits it to be expanded in a mold that reproduces the patient's morphology. This preform has the general shape of a three dimensional hollow body, more particularly, a hollow, tubular or approximately tubular form, more particularly still, a hollow, tubular or approximately tubular form which is cut on the upper anterior part to form an opening.

Traditionally, such apparatuses are tailor-made, created in a laboratory and therefore, piecemeal, starting from formed molds based on research models which have themselves been formed based on an impression or impressions

made in the practitioners office by the same.

Several apparatuses are generally necessary during treatment, to follow changes in the patient's morphology. The need to produce a new apparatus during treatment may also come from the need to move the fastening hooks due to a change in the environment (for example, with the appearance of wisdom teeth or with shifting of teeth). Each time a cast must be taken to produce a model, then a mold, and then the final apparatus must be produced.

More specifically, the traditional process for manufacture is a contact molding process. It occurs in four steps:

-Construction of the mold:

The practitioner makes a casting of the upper maxilla and possibly a casting of the lower maxilla of his patient, most often with alginates due to their rapid polymerization and biocompatibility properties. These castings act as a base for the production of a model in one or two parts which is most often in plaster, completed using wax that sticks easily and/or is easily deformed. This requires that the technician have great technical proficiency, integrating brief perceptions, dexterity, and experience. The technician, also using wax, positions the fastening systems (or fastening hooks and pins), generally metal wires which shall then be duplicate molded and shall perform the fastening function of the completed apparatus in the patient's mouth as well as any other additional necessary piece.

-Contact molding

A resin with two components is used, a solid powder and a fluid, adapted to contact molding of traditional orthodontic pieces. Work is conducted with successive passes of dampening by the liquid using a pipette and/or dusting with the solid.

However, the shape of the hollow body with variable thickness in certain apparatuses such as the N.L.E. by Bonnet results in special difficulties during production

since the different areas of the apparatus have quite varied orientations and curvature radii:

(i) A compromise must be found between passes that are too liquid or too thin or of such small surface that multiples are needed, thus lengthening the operating time, and passes which are too thick or too pasty which creates irregular upper thicknesses that will then need grinding.

(ii) It is difficult to estimate or measure the deposited thicknesses to inspect ones work as it progresses,

(iii) A choice must be made between molding of all passes in a single operation lasting several minutes or up to a quarter of an hour followed by a single final polymerization or molding with several very brief operations each lasting approximately a minute with as many intermediate polymerization phases in an autoclave pressurized above atmospheric pressure (otherwise gas bubbles arise deterring from the piece's final appearance). In the first case, one obtains a piece having irregular transparency and which is little flattering, in the second case, the production time, and therefore the cost are noticeably higher.

- Mold ejection and finishing

The blank is ejected from the mold, then finishing takes place using machining and grinding. The shape of the preform being somewhat removed from the final piece, finishing is a long and delicate operation generating noise and dust. Since this pollution is incompatible with a dentist's office, finishing must take place in an area with specific equipment, namely, for example, a suction hood.

- There are variations in which the teeth and gums part of the lower maxilla model are used complementing the upper maxilla model. A filler material (for example, plaster) is used to complete the missing part in order to obtain a complete mold. In this case, the mold is completely exterior to the piece to be molded; the general accessibility and visibility are not as poor as in the preceding variation.

The apparatus is then equipped with hooks in order to be attached to the patient's mouth. Currently, there are mainly two types of hooks or claws or fastening systems, hereafter fastening hooks, (Step 1) used depending on the morphology and the dental age of the patient, in general made of stainless steel orthodontic wires:

- Lateral hooks (generally symmetrical, totaling 2)

They are used especially for young children. They are anchored in the apparatus at one end which is inserted in the lateral wall of the apparatus, the other end being inserted elastically into a diastema to attach the apparatus to the mouth. They are generally cold-formed using the Sahar method, meaning that the beginning of the emerged part has a zigzag shape such that it may be deformed by the practitioner to adjust the tightness of the anchoring when it is first placed in the mouth and on the following visits depending on the changes in the patient's oral environment, all without changing the anchoring, that is, the position of the part of the hook included in the apparatus. In the thickness of the outside wall of the apparatus, a hollow is reserved to lodge this zigzag whose shape changes during the apparatus' life.

- The posterior hooks (generally symmetrical, totaling 2)

They are anchored in the apparatus such that the wire exits at the rear of the apparatus approximately in the horizontal occlusion plane. The wire then generally follows the contours of the teeth which are farthest back (for example, the 6 year tooth or the 12 year tooth), then it comes to exert pressure from the outside on the tube of a ring. It is formed in such a way that with the slight symmetrical forces of the two posterior right and left hooks pressing upward and outward in reaction to the apparatus it is kept in position against the palate.

This production method offers certain inconveniences. In effect, production costs are high (made to order), the appearance and quality of the product are often insufficient (manual), at times, considerable finishing is needed, delays are excessive. Furthermore, the alginate cast is destroyed when the plaster model is released from the mold. Therefore, the model must not be damaged so that the patient does not have to undergo the procedure again. So, this plaster

handling is therefore even more difficult, and requires even more attention and time. Finally, the process generates noise, dust and odors (solvents, etc.).

Attempts at thermoforming have been made, in order to eliminate certain drawbacks linked to the conventional process. The thermoforming technique is widely used for the production of orthodontic appliances. It is described in many general works. In the field of orthodontics, it is possible to cite the work by Michel AMORIC: "Thermoformed Orthodontic and Orthopedic Splints," 1993, Editions SID.

The principle of this technique is that a flat plate of constant thickness is used as the base material. Using a conventionally produced mold, the plate is subjected to deformations in order to obtain an appliance of appropriate shape.

Not all appliances can be obtained by this method. In particular, this method is not effective for appliances in the form of hollow bodies and having variable thickness. In fact, the stretching that the plate must undergo in these specific cases is fairly substantial and hence difficult to obtain without tearing. Above all, the thicknesses cannot be controlled, since they are simply a function of the elongation required to obtain the desired shape, and are therefore irregular since not all of the areas are stretched in the same way. This technique is therefore only suitable for a certain number of cases.

The variant that consists of using an appliance with two parts, i.e., two base plates producing two semi-appliances that are assembled, is not suitable either. It makes it possible to reduce the stretching sustained by the plates, and hence the risk of tearing and the problem of overly irregular thickness, but the problem is partially transposed to the joint of the two semi-appliances obtained. In fact, the problem in this case resides in the precision and the strength of the joint by means of adhesive or solder, especially since it is also necessary to implant in this joint area the fastening hooks for holding the appliance in the patient's mouth.

The thermoforming methods used up to present day therefore do not allow the production of apparatuses with hollow bodies and variable thicknesses and the risks of damaging the sole plaster mold are significant.

The invention allows these problems to be solved by proposing a three dimensional apparatus that can be produced in series, thereby at low cost; this apparatus is called a preform. This preform is different from a flat plate and has a general shape permitting it to expand in a mold that reproduces the patient's morphology. This preform has the general shape of a three-dimensional hollow body, more particularly, a hollow, tubular or approximately tubular form, more particularly still, a hollow, tubular or approximately tubular form which is cut on the upper anterior part to form an opening. Said preform may then be perfectly adapted to each patient in the practitioner's office or in the prosthesis maker's laboratory by a deformation process including expansion that is quick and easy to implement, in a mold constructed starting with a plaster model, without any risk for said plaster model. It allows a functional apparatus to be obtained which cannot be obtained by traditional thermoforming starting with a flat plate.

The term "technician" shall refer to the person transforming the preform into a functional apparatus, whether this is the practitioner in the office or the prosthesis maker in the laboratory.

More specifically, this preform is manufactured in a biocompatible material due to the at times prolonged contact with a human cavity [the mouth]. It must, in this respect, meet current applicable standards. It may be a thermosetting or thermoplastic type of plastic material deformable through expansion and obtained, for example, by injection or any other appropriate industrial process (first stage processing), and presenting a three dimensional shape such that its deformation easily allows for the creation of the final apparatus adapted to each patient. This deformation or second stage processing, which includes expansion, is performed rapidly and easily by the technician according to the patient's morphology.

In this description, expansion of the preform means the volumetric development or deformation of the preform.

The invention has merit in that it has removed the disadvantages related to the necessary production and individualized adaptation of an orthodontic apparatus by permitting low-cost series manufacturing of a preform which shall then be easily adaptable to the patient by the practitioner or prosthesis maker in order to obtain, after finishing, a functional apparatus with a hollow body of varying thicknesses that would not be possible with the simple deformation of a flat plate, and, in some variants (particularly if thermoplastic material is used) is capable of being equipped with fastening hooks in the mouth by a process which allows changes in anchoring points.

The production cost is therefore lower; the delays are shorter; the process is clean (without dust, noise, or odor) and simple to implement, without risk to the plaster model, and facilitates the technician's work.

The shape of the preform is defined while taking into account mean deformations to which it shall be subject during second stage processing--for example, reduction of thickness and width variables of the walls, according to the desired functional apparatus. It is therefore possible to envisage a preform for such an apparatus and for patients of a given size or gender or age. Thus, series production of the preform is allowed even while limiting the deformations that it shall undergo, thereby the lengths and complexity of the second stage processing.

In one variation, it is also possible to imagine having the preform manufactured and delivered to the technician in a developed flattened shape, thus generally shaped in two dimensions and no longer in three dimensions. This is called a developed preform. Such a case shall be detailed later making reference to figures. The developed preform is then given a volume by the technician by rolling or bending around an appropriate gauge which may be a controlled expansion core to create the

preform as such. Thus, the production cost is decreased, as is the volume of the preform manufactured in series which, here, is a developed preform. Furthermore, this structure in two dimensions facilitates certain manipulations by the technicians (preparation of an opening, etc.). However, the possibility to define the thickness at each point of the preform is retained since the developed preform may itself be of a variable thickness according to each area. The connection (cross-section) to recreate the hollow body is located in the least deformed area during expansion, for example the bow of a slide in the case of Bonnet's N.L.E. The weld is performed by hand using pressure (for example, a self-adhesive effect, by application of a solvent or glue adapted to the material of the developed preform) such that it then resists expansion.

The second stage process is dependent on the plastic material used. If thermoplastic plastic materials are used, the second stage process may be carried out with techniques belonging to blowing, thermoforming, injection blow molding, even mechanical means or any other appropriate means. If thermosetting material is used, the second stage process may be carried out with techniques similar to compression, dry bag molding, vacuum molding, preforming on a diaphragm, or any other appropriate means.

This second stage process shall be performed by the technician, that is to say, by the practitioner, in his office or by the prosthesis maker in his laboratory, rapidly and easily by a "clean" process, that is to say, without dust, noise or odor, within very short time frames and in conditions that allow perfect adaptation to the patient's morphology.

Furthermore, the different apparatuses necessary during treatment due to changes in the patient's morphology can be produced successively based on the first apparatus produced from a preform. Thus, the first apparatus shall become the preform for the second apparatus which shall be necessary some months later, this second apparatus becoming in turn,

the preform for the third, etc. The transformations shall therefore be rapid since it is not necessary to start from scratch each time, unlike present day practices.

The process of the invention also allows the anchoring position of the fastening hooks to be moved slighting in the apparatus at the time of installation in the mouth and/or during treatment, thus, in some cases, avoiding the manufacture of a new apparatus.

Other characteristics and advantages of the invention shall be better understood by reading the description which follows, referring to the included figures in which:

- Figure 1A shows a frontal cross-section (A-A axis), a preform without opening pursuant to the invention, adapted to obtain Bonnet's N.L.E.

- Figures 1B and 1C show this preform respectively in a sagittal cross-section (longitudinal vertical) (B-B axis) and horizontal longitudinal cross section (C-C axis),

- Figure 2A shows a side view of a preform according to the invention, provided with an opening,

- Figure 2B shows the preform in 2A seen from above,

- Figure 2C shows a perspective view of the preform in 2A,

- Figure 3 shows a mechanism for the transformation of a preform into a functional apparatus following the patient's morphology,

- Figure 4 shows a cross-section of a controllable expansion core used in a process according to the invention,

- Figures 5A, 5B and 5C show the core from figure 4 in cross-sections that are respectively frontal, longitudinal horizontal, and saggital (longitudinal vertical),

- Figure 6 shows a developed preform according to the invention,

-Figure 7 shows[1] the preform obtained by rolling/bending of the developed preform in figure 6,

[1] TN: error in original: represente represente

- Figure 8 (8A + 8B) shows a right Sahar's hook inserted or anchored in an apparatus according to the invention (seen from behind and seen from the right),

- Figure 9 (9A + 9B) shows a right lateral hook before anchoring in an apparatus according to the invention by a hook anchoring mechanism containing two fork-shaped extremities (seen from the left and seen from above),

- Figure 10 (10A + 10B + 10C) shows a right rear hook with returning forks inserted and anchored in an apparatus according to the invention (seen from the rear, seen from the left, and seen from above).

Figures 1 and 2 describe preforms (1) according to the invention, adapted to obtain Bonnet's N.L.E.

The preforms pursuant to the invention may have varying shapes, depending on the function of the shape of the apparatus obtained from the deformation of said preform. Furthermore, certain adaptations that are necessary in order to obtain a functional apparatus may be performed either at the preform stage or during the stage known as second stage processing, or after this stage. These adaptations may be made by cutting, machining, hot welding, or other processes. In a general manner, the preform has a shape that is as close as possible to the final form desired after deformation, in order to limit the number of operations to be performed by the practitioner or prosthesis maker all the while allowing a mass manufacture of the preform from the start. In one variation, the preform contains at least one opening.

Figure 1 shows a preform (1) pursuant to the invention, with a hollow approximately tubular shape, without opening, having one utilizable extremity (2) and one non-utilizable extremity (3), said non-utilizable extremity being eliminated after the second stage processing of the preform into an apparatus adapted to the patient.

Figure 2 describes another preform (1) according to the invention. This preform has an approximately tubular, hollow shape that is cut on the

upper anterior part in order to form an opening (8). In the apparatus, this opening (8) is intended to allow the patient's tongue to touch the front of the palate, in particular the palatine papillae. This opening is made prior to second stage processing, but it is also possible to make it after second stage processing. The preform may also eventually contain an excrescence (6) intended to wedge the preform in the mechanism made for carrying out the second stage processing, as well as initial holes (7) used to hold the fastening hooks of the functional apparatus in the mouth. The area (5) corresponds to the palate, and the area (4) to the lower part or slide of Bonnet's N.L.E..

In the entire description, spatial coordinates are given in reference to an orthodontic or dento-facial orthopedic apparatus worn by a standing individual. The terms lower, anterior, posterior, etc. are therefore explicit. The cross-sectional planes are themselves also made in reference to an individual theoretically wearing the apparatus, or by extension, the preform, even the controllable expansion core defined later which, at rest, has the same shape as the preform. A frontal cross-section is a cross-section of the frontal plane of this individual, a saggital cross-section is a cross-section perpendicular to the first in the vertical plane (vertical axis of symmetry), finally a horizontal longitudinal cross-section is a cross-section perpendicular to the frontal cross-section, but this time in the horizontal plane.

The invention also concerns the process for transforming said preform.

The transformation of the preform shall allow, after any adaptation (preparation of opening, initial holes, fastening of additional pieces, anchoring of fastening hooks, reduction of the surface in certain areas, hollows, polishing, etc.) the production of a functional apparatus. Certain areas of this apparatus shall be adapted precisely to the specific morphology of the patient, others shall respect the shapes defined by the rules of the art of orthodontics with respect to the shape of the oral cavity.

In the present case, area (5) which corresponds to the palate, must be precisely adapted to the patient's morphology. However, area (4) which corresponds to the lower part, that is, the part retreating from the lower maxilla, and the lateral areas, retreating from the gums and teeth, are the areas defined by the rules of the art rather than by the patient's morphology.

Figure 3 shows the mechanism allowing second stage processing of the preform so as to eventually obtain a functional apparatus, after adaptation (preparation of an opening, reduction in the surface of certain areas, etc.), and prior to installation in the mouth by the practitioner.

This mechanism includes a female mold (or a female mold system) made up of models (9, 10) generally in plaster of the patient's upper maxilla and lower maxilla. In order to create these plaster models, the impression or impressions made by the practitioner of the patient when he examined the case are used as a matrix. This mold may be completed or modified by the traditional mechanical means (machining, addition of metallic pieces, stuffing with flexible material, for example silicone in plates or strips of varying width, length, and thickness adjusted to control the space left free between the expanded apparatus and the patient's oral cavity, or other) so as to have, where necessary, interior shapes defined by the rules of the art rather than the patient's morphology.

The plaster models (9, 10) constituting the female mold are maintained solidly and precisely in position with respect to each other in natural occlusion or in the relative position chosen by the practitioner and defined for example by a "bite" on wax or by marking of models, by a fastening system (13), for example a mechanical system, so as to constitute the second stage processing mold. The lock system may also fulfill the function of support and orientation with respect to the vertical of the ensemble.

The preform (1) is placed in the female mold (9, 10).

It may be modified prior to second stage processing to give it a morphology more favorable to obtaining the final form, such as for example, by creating an opening. All modifications or adaptations which can be performed prior to second stage processing will limit the number of operations after second stage processing.

Second stage processing depends on the material used for the manufacture of the preform. It includes deformation by expansion of the preform in order to obtain an apparatus adapted to the patient's morphology and to the rules of the art of orthodontics.

More precisely, it includes the following stages:

- creation of a female mold based at least in part on the study models made from castings (in general with alginates) made by the practitioner of his patient,

- positioning of the preform in the female mold,

- expansion of the preform until it has reached the desired volume,

- ejection from the mold of the apparatus which becomes functional after finishing.

Regardless of the material used, the process includes a main stage of expanding the preform. When a thermosetting product is used, the process also includes a polymerization step prior to ejection from the mold,

The expansion may be performed with heat. In this sort of process, the preform is brought to the temperature for deformation of its constitutive material before the expansion stage, either after or before the positioning stage in the female mold.

It should be emphasized that the step of bringing the preform to the temperature for expansion and the expansion step are not necessarily performed in the same mechanism. It is, for example, possible to bring the preform to the expansion temperature in an oven then move it to the mold for expansion.

The preform is brought to the expansion temperature by the action of radiation (for example, in an oven, for example, an infrared oven) or a heat carrying fluid provided by a tube (12). The radiation used may also be of the microwave or ultraviolet type. The heat carrying fluid may, for example, be water brought to 100°C. In one production mode, the heat carrying fluid mixes with the expansion fluid.

The expansion may take place through the intermediary of an expansion fluid, for example compressed air or water, or even mechanically, until the preform has attained the desired shape, that is, until it is pressed at least in part against the inside of the mold. The expansion may also be limited by a controllable expansion core such as is described later. In this case, the expansion shall be controlled both by the mold (in certain parts) and by the controllable expansion core (in other parts).

The expansion may be performed by any method which allows the preform to take on the desired shape. This means may be a mechanism for expansion by movement of mechanical pieces changed by the technician during the expansion phase. In another method of production, expansion takes place through the inflating of an expansion core (14) presenting an empty space (17) within, placed beforehand inside the preform (1) and inflated by an expansion fluid. This core may be made of an elastomer material or any other material resistant to the expansion temperature. In the case depicted here, the core is held in position during expansion by a retaining plate (15) contiguous with the feed tube of the expansion fluid (for example, compressed air) (11) itself attached to the support (13). The end of the preform may be held in position by the

intermediary of the excrescence (6) or by a part of the expansion core (14).

Such an expansion core may be produced by injection of an elastomer that is resistant to the expansion temperature, such as, for example, silicone, polyurethane, or nitrile. Production of the injection mold is based in traditional techniques that are not described in detail here. For example, it is possible to use injection or liquid silicone in a mold, for example, made of Plexiglas (for better visibility) containing a primary core of paraffin that is then eliminated with heat after cold curing or polymerization; or still by dipping with a primary core equipped with reinforcements, that is to say, without a mold. The primary core shall necessarily be meltable or destructible in order to create the necessary space (17) in the expansion core.

The expansion core may be a simple spherical or cylindrical shape of even thickness, but an evolved core or a controlled expansion core may also be used. Such a controlled expansion core is described in figures 4 and 5A to 5C.

This evolved core (16) contains at least one means for controlling its expansion, for example, an increase in the thickness of its wall in certain areas and/or introduction in its wall of rigid reinforcements, for example, made of metal.

Preferably, such a core at rest would have the precise shape of the preform. It would thus allow the prehension of this preform and its movement and rapid positioning during handling, specifically during heat induced expansion, between bringing it to the expansion temperature and the expansion, that is to say, when the preform is hot.

Bringing it to the expansion temperature may therefore be performed on the preform alone (outside of the mold) for example, in an oven and for example by infrared radiation, and may be selective, that is to say, favoring the areas which are to undergo high expansion. In the case of Bonnet's N.L.E., the areas undergoing the strongest deformations,

therefore those that shall be heated the most, are the upper edge of the slide and the upper posterior part of Bonnet's N.L.E. (which will touch the patient's palate).

The core may also contain metallic reinforcements such as spring bands (19) which, in some areas, will allow better control of deformations undergone by the preform. We refer to "controlled expansion", meaning anisotropic expansion. The expansion of the preform itself shall therefore be controlled at least in part by the core and not solely by the mold. Thus the core may replace the mold in the areas which must respect the rules of the art rather than the exact morphology of the patient: in these areas, the metallic reinforcements shall aid in the prevention of some undesired deformations. This shall allow the molds to be simplified. The element (20) serves to maintain the preform in position during expansion.

Furthermore, the core may contain a rigid tube (11), for example, in stainless steel, pierced with one hole (18) which shall allow the expansion fluid to arrive.

As an example, an evolved core used in the development of a Bonnet's N.L.E. could have the following characteristics: high thickness and metal reinforcement at the front of the slide, decreasing lateral thickness and elastic metallic reinforcement, inserted metal tube, high posterior thickness, low thickness above and below.

When the utilizable end of the preform is closed (Fig. 1), the expansion core is not needed. Compressed air arrives directly into the preform (1) from its open end (3) adapted to the compressed air feed tube (11) by a sealing mechanism for example, of the serflex variety.

When the preform is manufactured using a thermosetting material, expansion is accompanied simultaneously or afterwards by a polymerization triggering mechanism which may be, for example (i) an

increase in the temperature of the expansion mold + preform + any ballonet system., or (ii) an electromagnetic source such as microwaves or ultraviolet radiation emitted by a source placed in the core or in the preform and powered from within the compressed air feed tube (11).

After expansion, which allows the preform to reach the desired shape, and eventually polymerization, the piece obtained is ejected from the mold by opening the sealing system. In the case of heat induced expansion, the assembly is cooled prior to the piece being ejected from the mold in order to solidify the obtained shape.

This piece may then be finished or machined by any traditional process, such as, for example, polishing, deburring, localized heating by microguns using hot air or other substances, in order to obtain a functional apparatus adapted to the patient. This stage of finishing is shorter than in traditional processes, since the piece obtained is already very close to the final shape precisely adapted to the patient.

In the case that the preform is closed, the opening(s) in the piece obtained are prepared after the second stage processing by cutting, and the useless parts are eliminated (window, non-utilizable extremity) or the surface of certain areas is reduced, then finishing is conducted as described previously.

Finally, if necessary, the anchoring of the fastening hooks or of any other additional piece is made in any initial holes planned in the preform, or holes that are pierced after second stage processing, then glued or welded into position.

As specified above, the invention allows for the same apparatus to be used either during treatment of the patient, or by evolving it according to changes in morphology; the first apparatus produced serves as a preform for the second, itself serving as preform for the third and so on and so forth. It is therefore no longer necessary to produce a new apparatus after each stage. At the same time, it is essential to plan for fastening hooks whose anchoring points may be moved over time as a function of the changes in the patient's morphology and therefore as a function of the changes in the apparatus.

One of the purposes of the invention is therefore to offer an orthodontic apparatus obtained by the process described, and based on the described preform, with fastening hooks with moveable anchoring points.

In the basic version of such an apparatus, that is to say, using a thermoplastic material, the best process for fastening is welding, performed using one and/or the other methods indicated below.

Welding or heat-driven insertion of hot melt plastics requires two complementary and simultaneous functions:

- heating which may be obtained by any appropriate means, for example, mechanically by ultrasound, or electrically using the Joule effect, and

- transmission of the insertion force in the apparatuses and eventually the mechanical positioning of the piece to be inserted during cooling.

Three processes (and their mechanisms) are described below in the version of heating by the Joule effect, which is easily applicable to hooks and wires made of stainless steel.

In all three cases the mechanism for supplying the electric heating energy also provides stable mechanical positioning. The supply of electric energy may be provided by a portable current generator hand held by the technician (for example an instantaneous soldering iron designed or regulated so as to deliver an intensity which provides the piece to be inserted with the adequate temperature (approximately 5 amperes, 200°C)), containing a pair of rigid conductors. In another mode of production, it may contain a mechanism called a gun which mechanically holds a pair of rigid electric conductors connected by flexible conductors to a fixed generator. The extremities of the rigid conductors

are set-up so as to transmit the desired mechanical forces exerted by the technician to the hook which is to be inserted.

The three mechanisms described differ in their method of transmission of the mechanical forces to the piece to be heated and anchored and therefore in the shape of the extremities of the rigid conductors.

1. Mechanism with two extremities in the shape of a fork or a forked mechanism.

In order to ensure that the hook does not slip the extremity of each conductor has a shape adapted to the diameter of the wire or to the shape of the piece to be inserted, that is to say, the fastening hook. This shape provides stability to the mechanism's fulcrum on the piece to be inserted regardless of the force to be transmitted. Such a shape may, for example be in the shape of a fork. Such a mechanism shall be referred to by the term "forked mechanism".

Only thrust may be transmitted to the piece to be inserted.

At the end of insertion, the technician stops pushing, the electric circuit opens, heating stops, the piece is free in the locally melted plastic.

The excess melted matter collected on the surface may be removed or shaped with a spatula while still warm (for example, by a piece created or covered with PTFE or an other material that does not stick to plastic) by the technician to improve the mechanical strength and appearance of the insertion. In one variation the spatula work is performed with a spring mechanism eventually released by the technician at the same time as the heating current is cut.

In order to control the degree of freedom and to avoid instability in the piece which may turn around the axis defined by the two forks during insertion, it is preferable to have recourse to a supplementary action, for example, holding the emerged extremity during the operation.

In this production method, the contact areas of the piece are finally included and the piece cannot be recuperated or moved by the same process since electric contact is no longer possible without machining the

apparatus to bare the contact areas and the system does not allow extraction forces to be exerted.

Figure 8 (8 A and 8B) shows a the right lateral view of a Sahar's hook (25) inserted or anchored in an apparatus (35) according to the invention, more specifically, around a lateral area (24) of the apparatus near the occlusion plane. The hook (25) includes a segment to insert (28) and a zigzag (26). This zigzag is inserted in a hollow (27) in the area (24) of the apparatus (35).

Figure 9 (9A and 9B) shows a right lateral hook (25) before insertion or anchoring in the lateral area (24) of an apparatus (35) by a forked insertion mechanism. In the mode of production shown, the extremity of each rigid conductor (29) of the insertion mechanism has the shape of a fork (30).

2. Mechanism containing two extremities in the form of a clamp, the piece to be inserted (fastening hook) containing a bent-back segment.

The extremity of each conductor is prepared to clamp the piece to be inserted (for example using a clamping screw of the sort for an electric box, a micro screw or spring clamp, a micro three-jaw chuck, or any other mechanical system). In a complementary manner, the piece to be inserted contains a bent back segment which remains outside of the apparatus at the end of insertion and the two segments are clamped by the mechanism. This type of hook is referred to by the term "hooks with bent-back segments".

At the end of insertion, the technician cuts the current (for example, using the trigger of the gun), the piece remains held by the mechanism which continues to clamp the piece, the positioning of the piece may therefore be adjusted precisely in all degrees of freedom during the cooling phase.

The excess melted matter collected on the surface may be removed or worked with a spatula as described previously.

Finally the two extremities of the inserted piece are freed by the opening of the clamps and remain emerging from the apparatus. They are, of course, designed and/or finished following traditional methods (loop or end loop) so as not to injure or bother the patient.

It is therefore possible to reposition the gun again later, to clamp the piece to make electric contact, to heat the piece and slightly move it in the apparatus. This facilitates adjustment of the installation in the mouth and the slight displacement, even replacement, of the hook for later follow-up care of changes in the patient's morphology.

These hooks with bent back segments, the process and the corresponding mechanism are quite appropriate for rear hooks since it is very useful to be able to move them or replacement during the life of the apparatus as was explained above.

Figure 10 (10A, 10 B, and 10C) shows a rear right hook (25) with a bent back segment inserted in an apparatus (35) according to the invention, in one part of the apparatus with sufficient thickness, in general, close to the plane of occlusion. This hook with a bent-back segment has a primary segment (31) forming a contour along the teeth, an area (32) of pressure of the hook on the teeth, as well as a bent back segment (33) at the end, formed in a loop. Between the primary segment (31) and the bent back branch (33) lies the area (34) of the hook (25) which is inserted in the apparatus (35).

3. Mixed weld

In this case, each extremity of the mechanism is prepared following one of the above mechanisms, that is to say with fork and clamp. This process is generally quite appropriate for lateral Sahar's hooks. In effect, this configuration allows good handling of the piece to be inserted by the clamped segment and to completely insert the other segment.

In one variation, the preform is manufactured and delivered to the technician in the developed form, that is, in two dimensions. This is a developed preform.

Figure 6 describes one such developed preform adapted to obtain a bonnet's N.L.E.. Area 21 is the semi-developed half of 21G or right 21D of

the taper of the slide, area 22 is the semi-developed left 22G or right 22R of the palate. Areas 23 constitute the bow of the slide. The dotted lines represent the right, left and central (axis of symmetry) axes for bending.

The developed preform is then given volume by the technician to create the preform as such shown in figure 7. The taper of the slide 21 and the palate 22 can be seen. The dotted line represents the right axis of bending. The connection (cross-section) to create the hollow body is located in the area that is least deformed during expansion, on the bow 23 of the slide 21 in this case of Bonnet's N.L.E. The weld is performed by hand pressure (self-adhesive effect) such that it then resists expansion.

This invention also concerns personalized orthodontic or dento-facial orthopedic apparatuses obtained by said transformation process starting with said preform. In a special case, such an apparatus is a Bonnet's Nighttime Lingual Envelope or N.L.E.

This invention covers the different adaptations, applications and modes of implementation which may be considered and which are known by people in the trade.

Thus, it is possible to produce several types of preforms, with different shapes and thicknesses which may be easily adapted to the desired function, to the size and morphology of patients (adults, children, etc.) and to the deformations that the preform shall undergo during second stage processing.

Similarly, the initial holes created to receive the fastening hooks when necessary may be eliminated or replaced by other mechanisms or arrangements (for example, impressions) facilitating the insertion of fastening pieces (bars with holes or pins) during (via duplicate molding) or after (gluing, screwing, welding, etc.) second stage processing.

The preform's surface may include guides, such as bumps or hollows intended to guide the technician during cutting operations, before or after second stage processing (preparation of the window, reduction of the surface in certain areas, etc.).

The material chosen to produce the preform may vary. In the case of thermoplastic material, it is possible, for example, to use polyethylene, polypropylene, methyl polymethacrylate or any other appropriate material. With regards to the use of this kind of thermoplastic material, we should refer to M. AMORIC's above mentioned work. In the case of thermosetting polyurethanes or methyl polymethacrylate or any other appropriate material may be used.

It is possible to use different colors or loads, even different flavors to make the use more attractive especially for young patients.

The preform may, in some parts, in particular in the areas where the surface geometry is determined by the rules of the art and not by the patient's morphology, have the definitive shape of the functional apparatus. For example, in the case of Bonnet's N.L.E., the lower part or slide has a shape close to that of the body of a cone.

The female mold may be created from a single model of the upper maxilla as first half-mold, and by an assembly of pieces having standard shapes following orthodontic rules or specific to the patient for the second half-mold. The controlled expansion core can also act as a mold in some areas.

Heating of the preform may take place by several processes, for example, hot air or other gas, hot liquid, electromagnetic radiation (such as infrared, microwaves or ultraviolet) emitted by a source external to the core or powered internally by the air feed tube.

The flow of the heat bearing fluid, which may be the expansion fluid, may be external to the preform and/or internal by using the fluid feed tube and a second tube inside of the first for the outflow. The same is true for cooling after transformation.

CLAIMS

1. Preform (1) allowing the obtainment after deformation of customized orthodontic or orthopedic dentofacial appliances, characterized in that it has the general form of a three-dimensional hollow body and in that it has a form that allows its expansion inside a mold reproducing the morphology of the patient.

2. Preform according to claim 1, characterized in that it has a hollow tubular or approximately tubular shape.

3. Preform according to any of claims 1 through 2, characterized in that it has a hollow tubular or approximately tubular shape, cut out at the top front part to form an opening 8.

4. Preform according to any of claims 1 through 3, characterized in that it is made of a plastic material of the thermoplastic or thermosetting type deformable by expansion.

5. Preform according to claim 4, characterized in that it is made of a thermoplastic material chosen from the group constituted by polyethylene, polypropylene, polycarbonates, methyl polymethacrylate, PVC, polyurethanes, or of a thermosetting plastic material chosen from the group constituted by methyl polymethacrylate and polyurethanes.

6. Preform according to any of claims 1 through 5, characterized in that it has on the surface guiding means, for example bosses or recesses, intended to guide the operator during the cutting operation, and/or pre-drilled holes (7) used to contain the adhesive paste for the functional appliance.

7. Preform according to any of claims 1 through 6, characterized in that it is produced in unrolled flat form before being shaped by the operator.

8. Preform according to any of the preceding claims, allowing the obtainment after

deformation of a Bonnet night lingual retainer (N.L.R.).

9. Process for producing a customized orthodontic or orthopedic dentofacial appliance, characterized in that it comprises the following stages:

- production of an expansion mold (9, 10) made at least partially from a design model or models made by the practitioner from the impression or impressions taken from his patient,
- positioning of the preform (1) according to any of claims 1 through 8 in the expansion mold,
- expansion of the preform until it has reached the desired shape,
- demolding of the appliance obtained, which becomes functional after finishing.

10. Process according to claim 9, characterized in that the expansion takes place with heat and in that the preform is brought to the softening point of its constituent material before the expansion stage, either before or after the positioning stage in the expansion mold.

11. Process according to claim 10, characterized in that the reaching of the expansion temperature is produced by the action of a radiation or a heat-exchanging liquid.

12. Process according to claim 11, characterized in that the radiation used is the microwave or ultraviolet or infrared type.

13. Process according to any of claims 9 through 12, characterized in that the expansion is produced by any appropriate means for obtaining the expansion of the preform to the desired shape.

14. Process according to claim 13, characterized in that the expansion is produced by the action of an expansion fluid or mechanically.

15. Process according to claim 14, characterized in that the expansion fluid is compressed air or water.

16. Process according to any of claims 9 through 15, characterized in that the expansion is produced by means of an expanding core (14) placed in the preform (1) and inflated by the expansion fluid.

17. Process according to claim 16, characterized in that the core has a controlled expansion (16).

18. Process according to claim 16 or 17, characterized in that the expanding core (14, 16) is made of a material resistant to the expansion temperature, for example an elastomer material.

19. Process according to any of claims 9 through 18, characterized in that the preform is made of thermosetting material and in that the expansion stage is simultaneously or subsequently accompanied by a stage for polymerizing the thermosetting material.

20. Process according to any of claims 9 through 19, characterized in that it also comprises, during the expansion, the insertion by duplicate molding of fastening pieces or complementary pieces.

21. Process according to any of claims 9 through 20, characterized in that the finishing stage comprises at least one of the following actions: creation of one or more openings, polishing, anchoring of fastening hooks, attachment of complementary pieces, elimination of the unnecessary parts, reduction of the surface of certain areas.

22. Process according to any of claims 9 through 21, characterized in that it comprises a stage for anchoring fastening hooks at movable anchor points.

23. Process according to any of claims 9 through 22, characterized in that the orthodontic or orthopedic dentofacial appliance obtained by the process during a previous cycle

is used as a preform.

24. Process according to any of claims 9 through 23, characterized in that the customized orthodontic or orthopedic dentofacial appliance obtained is a Bonnet night lingual retainer (N.L.R.).

25. Expanding core, characterized in that it is used in a process according to any of claims 16 through 24, and in that it comprises at least one means for controlling its expansion.

26. Core according to claim 25, characterized in that the means for controlling its expansion is chosen from among the following means, i.e., an increase in the thickness of its wall in certain areas and the insertion into its wall of rigid, for example metal, reinforcements.

27. Expansion device characterized in that it allows the expansion of the preform according to claims 1 through 8 until it has reached the desired shape, through the displacement of mechanical parts moved by the operator during the expansion phase.

28. Fastening hook for an orthodontic or orthopedic dentofacial appliance produced according to the process described in claims 9 through 24, characterized in that it comprises a branch called a return branch that remains outside the appliance after insertion.

29. Device for attaching fastening hooks to an orthodontic or orthopedic dentofacial appliance produced according to the process described in claims 9 through 24, characterized in that it comprises a device for supplying electrical heating energy and for stable mechanical positioning of the fastening hook to be anchored.

30. Device according to claim 29, characterized in that the supply of electrical energy is provided either by a portable current generator hand-held by the operator and comprising two rigid electrical conductors, or by a gun mechanically holding a pair of rigid electrical conductors connected by flexible conductors to a fixed generator.

31. Device according to claim 29 or 30, characterized in that the stable mechanical positioning is performed by the ends of the electrical conductors, which have the form of a clip or a shape adapted to the diameter of the wire or to the shape of the hook to be inserted, for example a fork shape.

32. Process according to claim 22, characterized in that the fastening hooks are attached according to claim 28 by means of an attaching device according to any of claims 29 through 31.

33. Customized orthodontic or orthopedic dentofacial appliance, characterized in that it is produced from a preform (1) according to any of claims 1 through 8 by means of a process according to any of claims 9 through 24 and 32.

34. Orthodontic or orthopedic dentofacial appliance according to claim 33, characterized in that it constitutes a Bonnet night lingual retainer (N.L.R.).

APPLICATION FOR PATENT

Title: Preform allowing the production of personalized orthodontic apparatuses following deformation, the apparatuses obtained and the process for their production.

Inventors and applicants: Maîwenn BONNET
François BONNET
Bruno BONNET

ABSTRACT

This invention pertains to the area of orthodontic apparatuses, particularly those that have been precisely adapted to the specific morphology of each patient.

The invention proposes a preform dissimilar to a plate; the form of which allows it to expand within a mold that reproduces a patient's morphology; it may be mass produced and easily adapted by the practitioner or prosthesis maker to each patient's morphology as well as orthodontic or dento-facial orthopedic apparatuses obtained from this preform and their manufacture process.

Such apparatuses are, for example, Bonnet's N.L.E. (Nighttime Lingual Envelopes - *Enveloppe Linguale Nocturne*) or any apparatus presenting a general hollow body form, possibly with one or more openings, varying thickness, and which, because of this specific geometry, cannot be produced from a model in the form of a flat plate.

Fig. 2C

09/423858

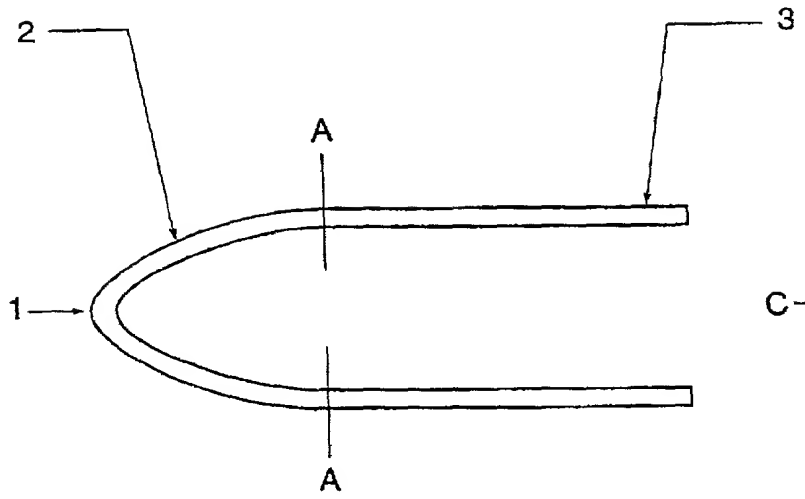

Fig. 1B

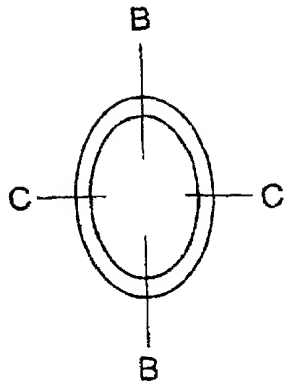

Fig. 1A

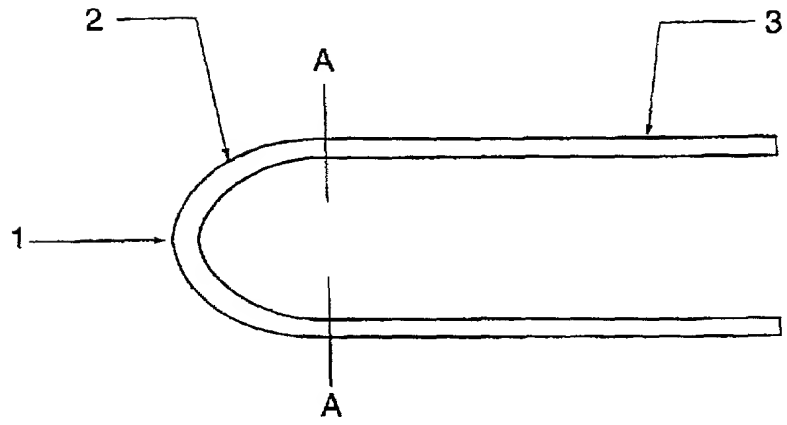

Fig. 1C

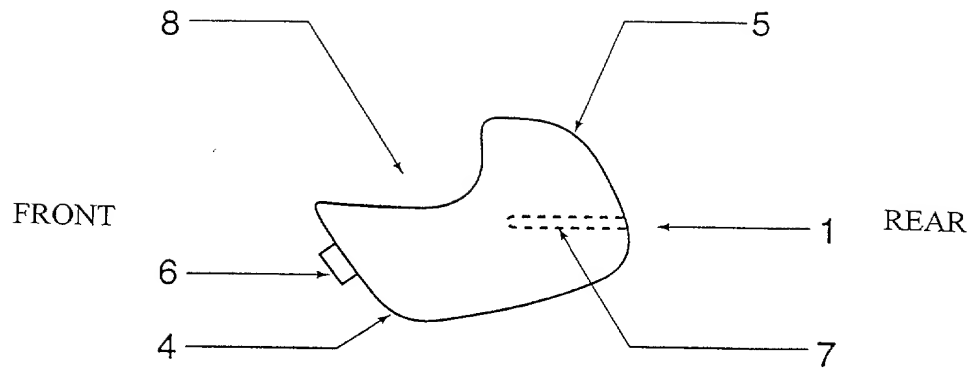

Fig. 2A

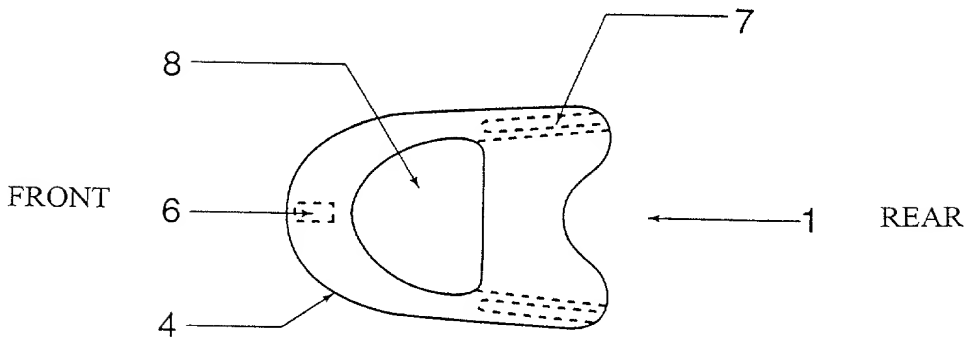

Fig. 2B

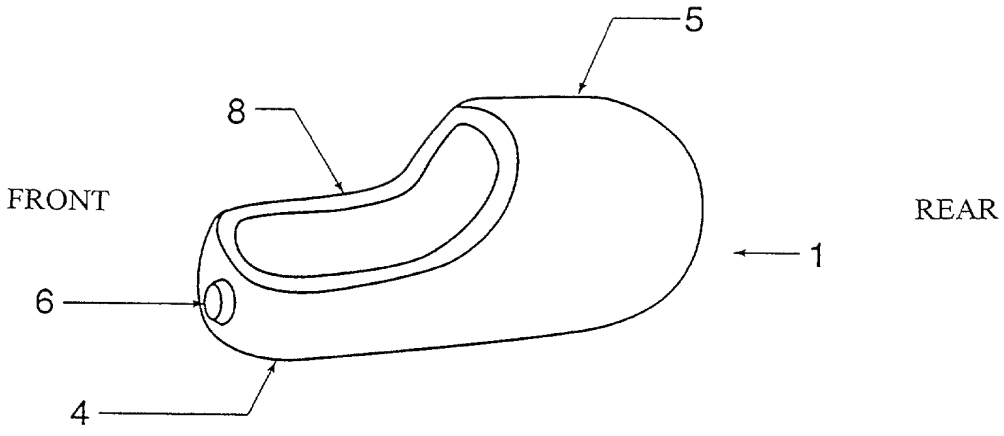

Fig. 2C

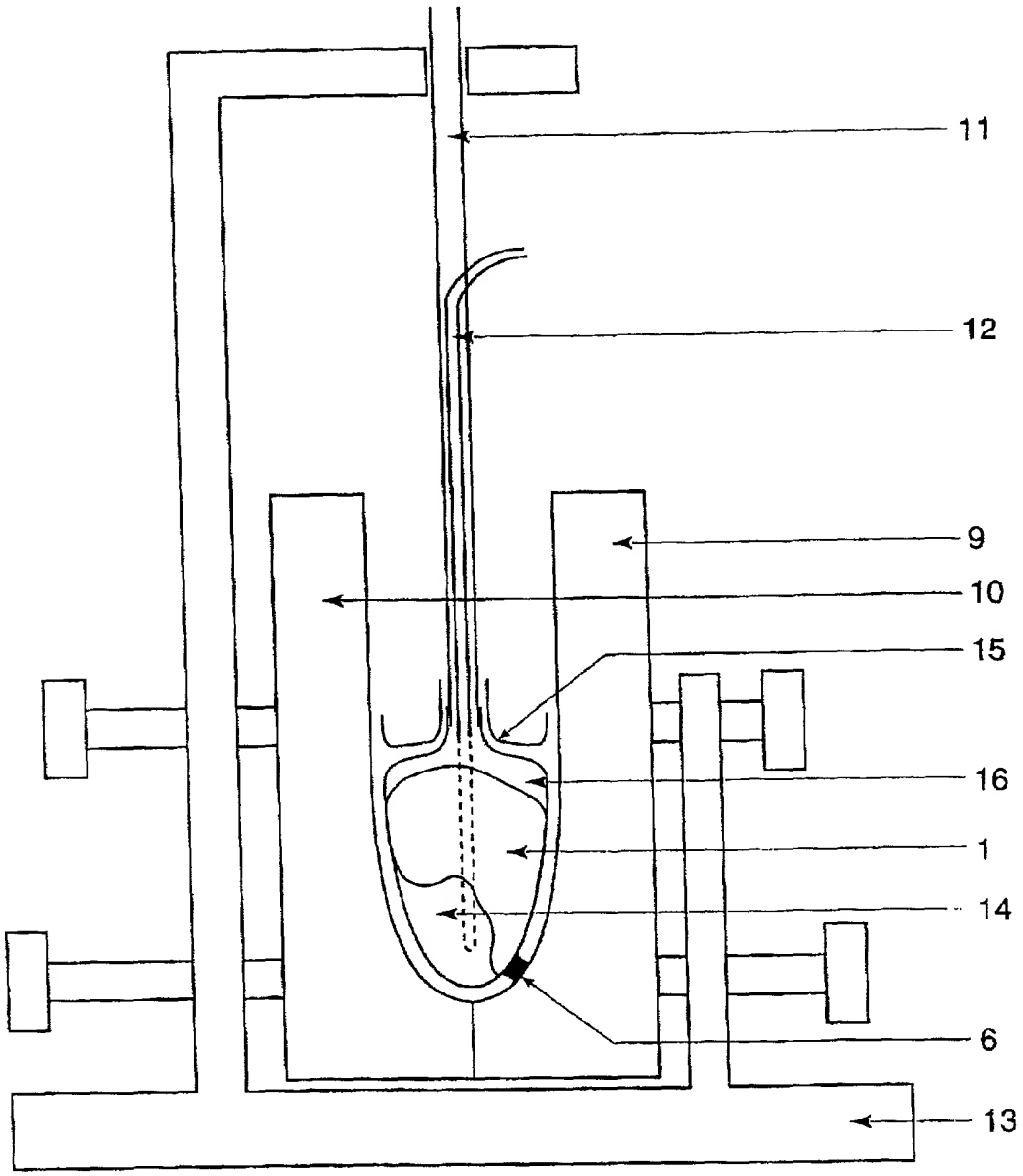

Fig. 3

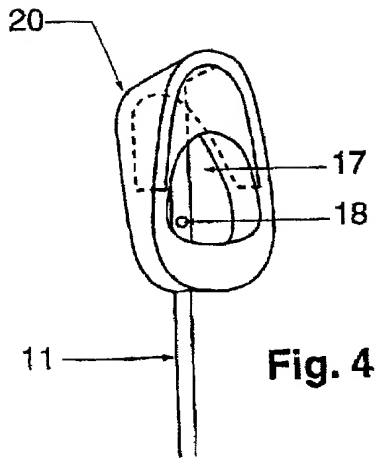

Fig. 4

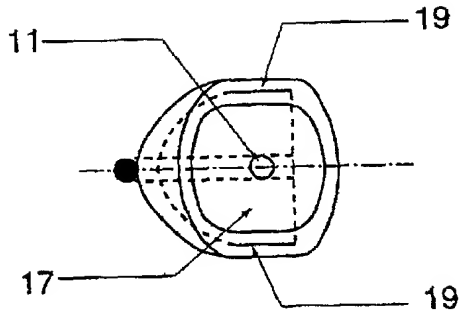

Fig. 5A

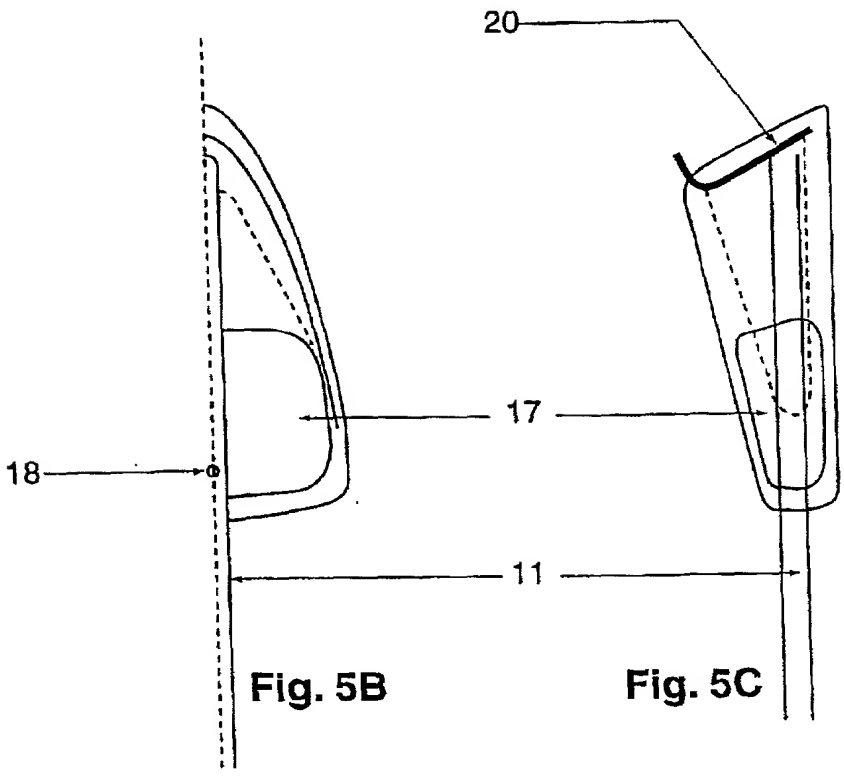

Fig. 5B

Fig. 5C

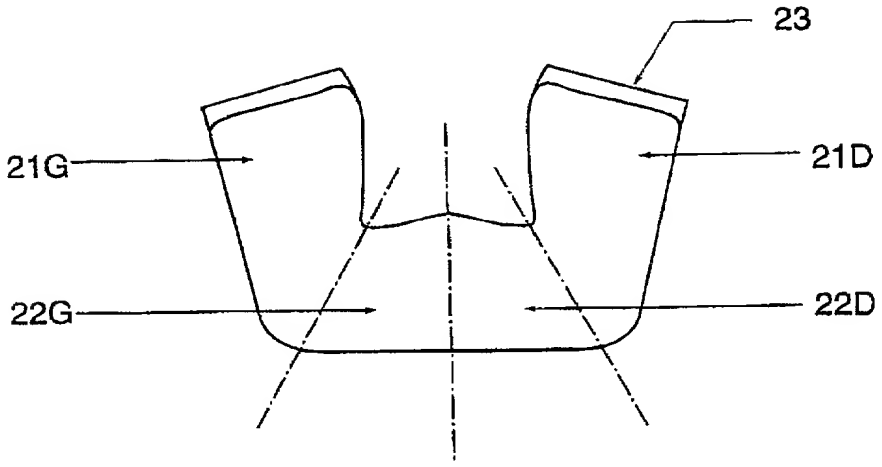

Fig. 6

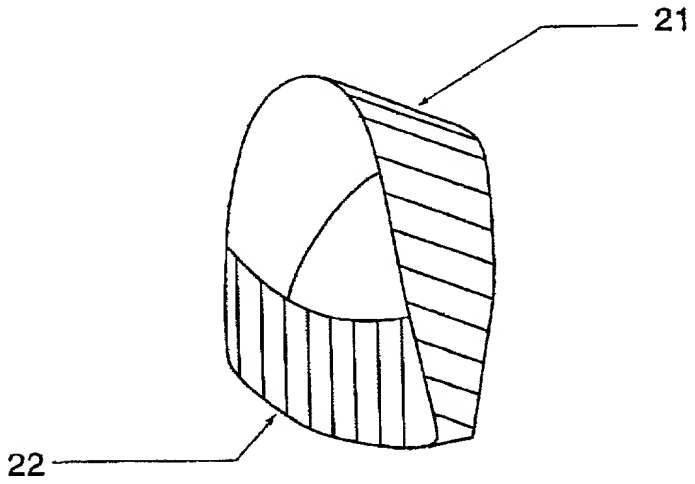

Fig. 7

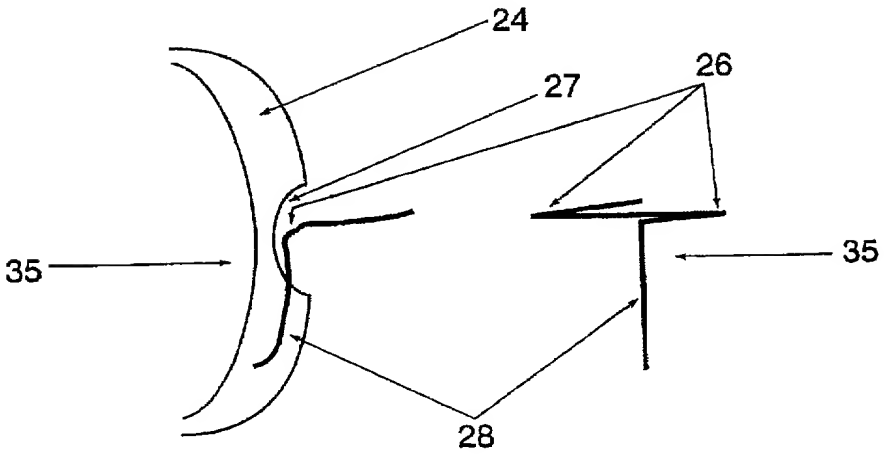

Fig. 8A

Fig. 8B

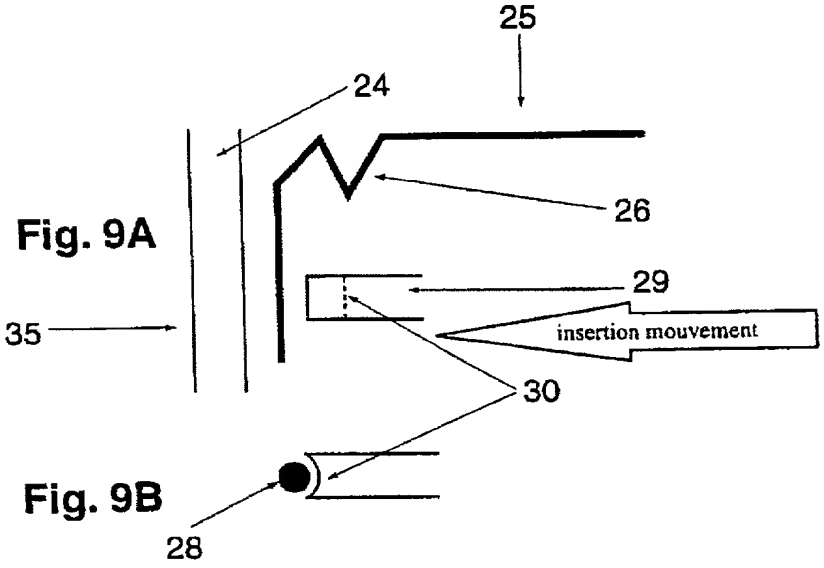

Fig. 9A

Fig. 9B

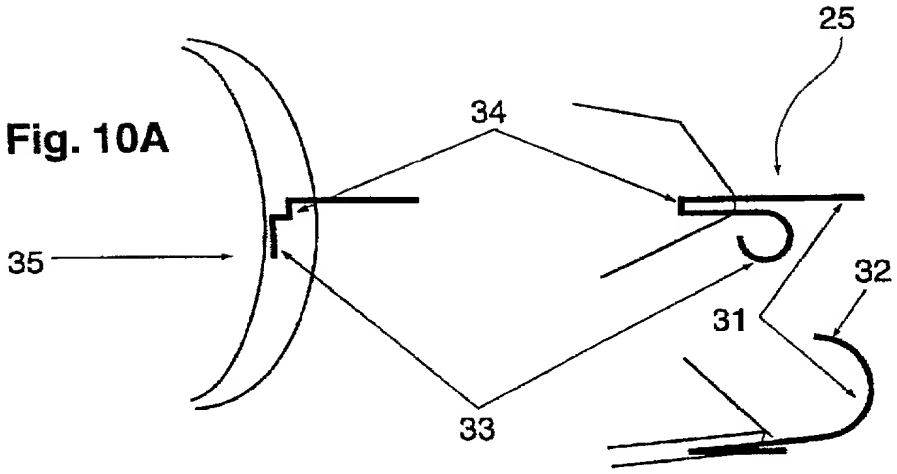

Fig. 10A

Fig. 10B

Fig. 10C

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I declare that:

My residence, post office address, and citizenship are as stated below next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled

PREFORM ALLOWING THE PRODUCTION OF PERSONALIZED ORTHODONTIC APPARATUSES FOLLOWING DEFORMATION, THE APPARTUSES OBTAINED AND THE PROCESS FOR THEIR PRODUCTION

[ ] the inventor's declaration for said application being executed concurrently with the execution of this instrument; said application to be filed in the U.S. Patent and Trademark Office;

[ ] said application having been filed in the U.S. Patent and Trademark Office on _____ and given Application No. _____;

[X] said application having been filed under the Patent Cooperation Treaty on May 15, 1998 and given Application No. PCT/FR98/00984, the United States of America having been designated.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge that duty to disclose information of which I am aware and which is material to the examination of the patent application in accordance with 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the space, any foreign application for patent or inventor's certificate, or of any PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Number	Country	Day/Month/Year Filed	Priority Claimed
97/06082	France	May 15, 1997	YES

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Serial Number	Filing Date

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States of PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information known to me which is material to the patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial Number	Filing Date	Status (patented, pending, abandoned)

Each undersigned applicant hereby appoints the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: **George H. Spencer** (Registration No. 18,038), **Robert J. Frank** (Registration No. 19,112), **Norman N. Kunitz** (Registration No. 20,586), **Gabor J. Kelemen** (Registration No. 21,016), **John W. Schneller** (Registration No. 26,031), **Marina V. Schneller** (Registration No. 26,032), **Robert Kinberg** (Registration No. 26,924), **L. Allen Wood, Jr.** (Registration No. 28,134), **Ashley J. Wells** (Registration No. 29,847), **James R. Burdett** (Registration No. 31,594), **Michael A. Gollin** (Registration No. 31,957), **Catherine M. Voorhees** (Registration No. 33,074), **Gary L. Shaffer** (Registration No. 34,502), **Chellis Erika Neal** (Registration No. 36,877), **G. Abe Zachariah** (Registration No. 38,366), **Patricia R. Brown** (Registration No. 39,012), **Julie A. Petruzzelli** (Registration No. 40,769), **Catherine A. Ferguson** (Registration No. 40,877), **Michael P. Leary** (Registration No. 41,144), **Michael A. Sartori** (Registration No. 41,289), **Zayd Alathari** (Registration No. 42,256) and **Fei-Fei Chao** (Registration No. 43,538).

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The undersigned hereby authorizes the U.S. attorneys named herein to accept and follow instructions from the undersigned's assignee, if any, and/or, if the undersigned is not a resident of the United States, the undersigned's domestic attorney, patent attorney or patent agent, as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys and the undersigned. In the event of a change in the persons(s) from whom instructions may be taken, the U.S. attorneys named herein will be so notified by the undersigned.

I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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Full Name of fourth inventor:
Inventor's signature Date
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Citizenship:
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